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DATE MAILED: 08/25/2010

NOTICE OF ALLOWANCE AND FEE(S) DUE

27387 7590 08/25/2010 LONDA, BRUCE S. NORRIS MCLAUGHLIN & MARCUS, PA 875 THIRD AVE, 8TH FLOOR NEW YORK, NY 10022

| EXAMINER | | | | | |
|---------------|--------------|--|--|--|--|
| STAPLES, MARK | | | | | |
| ART UNIT | PAPER NUMBER | | | | |
| 1637 | • | | | | |

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/573,134 | 12/18/2006 | Pablo Steinberg | 101215-219 | 4520 |

TITLE OF INVENTION: METHOD FOR CONDUCTING NON-INVASIVE EARLY DETECTION OF COLON CANCER AND/OR OF COLON CANCER PRECURSOR CELLS

| APPLN. TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(8) DUE | DATE DUE |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | YES | \$755 | \$300 | \$0 | \$1055 | 11/26/2010 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and I/2 the ISSUE FIEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

| appropriate. All further a indicated unless correcte maintenance fee notificat | correspondence includir of below or directed of | or transmitting the 18 ig the Patent, advance nerwise in Block 1, by | orders and notification of to (a) specifying a new correct | naintenance fees wi spondence address; | If be mailed to the and/or (b) indicatin | current c g a separ | ould be completed where correspondence address as ate "FEE ADDRESS" for |
|--|---|---|---|--|--|---|--|
| CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) | | | | Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. | | | |
| 875 THIRD AVE | UGHLIN & MARO E, 8TH FLOOR | | I be | Certify that this | ficate of Mailing o | r Transm | |
| NEW YORK, N | Y 10022 | | | | | | (Depositor's name) |
| | | | <u> </u> | | | | (Signature) |
| | | | | | | | (Date) |
| APPLICATION NO. | FILING DATE | | FIRST NAMED INVENTOR | | ATTORNEY DOCKE | TNO. | CONFIRMATION NO. |
| 10/573,134 TITLE OF INVENTION CANCER PRECURSOR | | ONDUCTING NON-II | Pablo Steinberg NVASIVE EARLY DETEC | CTION OF COLON | 101215-219 N CANCER AND/ | OR OF | 4520 COLON |
| APPLN, TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE | FEE TOTAL FEE | (S) DUE | DATE DUE |
| nonprovisional | YES | \$755 | \$300 | \$0 | \$105 | 5 | 11/26/2010 |
| EXAM | INER | ART UNIT | CLASS-SUBCLASS | 1 | | | |
| STAPLES | | 1637 | 435-091200 | • | | | |
| "Fee Address" indi PTO/SB/47; Rev 03-0 Number is required. 3. ASSIGNEE NAME AT | ondence address (or Cha 1/122) attached. cation (or "Fee Address 2 or more recent) attach ND RESIDENCE DATA | nge of Correspondence "Indication form led. Use of a Custome A TO BE PRINTED O | or agents OR, alternati (2) the name of a single registered attorney of a consistered attorney of a consistered name will be a consistent of the part | a 3 registered patent vely, the firm (having as a agent) and the name meys or agents. If n printed. | attorneys I member a 2 s of up to o name is 3 | | |
| PLEASE NOTE: Unit recordation as set forth (A) NAME OF ASSIC Please check the appropri | SNEE | | ee data will appear on the p OT a substitute for filing an (B) RESIDENCE: (CITY printed on the patent): | and STATE OR CO | OUNTRY) | | ument has been filed for up entity Government |
| 4a. The following fee(s) a ☐ Issue Fee ☐ Publication Fee (N) ☐ Advance Order - # | o small entity discount p | permitted) | 4b. Payment of Fee(s): (Plet A check is enclosed. Payment by credit car The Director is hereby overpayment, to Depo | d. Form PTO-2038 | is attached. | | |
| | SMALL ENTITY state | is. See 37 CFR 1.27. | ☐ b. Applicant is no lon | | | | |
| NOTE: The Issue Fee and interest as shown by the r | f Publication Fee (if requeords of the United Sta | uired) will not be acceptes Patent and Tradem | oted from anyone other than t ark Office. | he applicant; a regis | tered attorney or ago | nt; or the | assignee or other party in |
| Authorized Signature | | | | Date | | | |
| Typed or printed name | | | | Registration No |) | | |
| This collection of informa an application. Confident submitting the completed this form and/or suggestic Box 1450, Alexandria, V Alexandria, Virginia 223 | ation is required by 37 C iality is governed by 35 application form to the ons for reducing this bu- irginia 22313-1450. DC 13-1450. | EFR 1.311. The information U.S.C. 122 and 37 CF USPTO. Time will widen, should be sent to D NOT SEND FEES O | ntion is required to obtain or r R 1.14. This collection is est ary depending upon the indiv the Chief Information Office R COMPLETED FORMS To | retain a benefit by th timated to take 12 m ridual case. Any con er, U.S. Patent and T D THIS ADDRESS. | e public which is to inutes to complete, nments on the amou 'rademark Office, U SEND TO: Commi | file (and including int of tim .S. Depar ssioner fo | by the USPTO to process) gathering, preparing, and e you require to complete truent of Commerce, P.O. or Patents, P.O. Box 1450, |

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| LONDA, BRUCE S. | | | STAPLES, MARK | | | |
| NORRIS MCLAUGHLIN & MARCUS, PA 875 THIRD AVE, 8TH FLOOR NEW YORK, NY 10022 | | | | ART UNIT | PAPER NUMBER | |
| | | | | 1637 DATE MAILED: 08/25/201 | 0 | |

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 288 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 288 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Application No. Applicant(s) 10/573,134 STEINBERG ET AL. Notice of Allowability Examiner Art Unit MARK STAPLES 1637 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. This communication is responsive to 06/23/2010. The allowed claim(s) is/are 1-6,9 and 11-14. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). b) ☐ Some* c) ☐ None of the: 1. T Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: _____. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Attachment(s) 1. Notice of References Cited (PTO-892) 5. Notice of Informal Patent Application 2. Notice of Draftperson's Patent Drawing Review (PTO-948) Interview Summary (PTO-413), Paper No./Mail Date 3. Information Disclosure Statements (PTO/SB/08), 7. Examiner's Amendment/Comment Paper No./Mail Date 4. T Examiner's Comment Regarding Requirement for Deposit 8. X Examiner's Statement of Reasons for Allowance of Biological Material

/Mark Staples/ Primary Examiner, Art Unit 1637

08/11/2010

Other .

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DETAILED ACTION

1. Claims 1-6, 9, and 11-14 are pending and at issue.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Declaration Effective

- 2. The declaration under 37 CFR 1.132 filed 06/23/2010 is sufficient to overcome the rejection of claims 1-6, 9, and 11-14 based upon Salahshor et al. (1999), Davies et al. (June 2002), Kmiec et al. (WO200173002 published 2001), Shuber et al. (WO200118252 published 2001), Ferrie et al. (GB2327497 published 1999), Coste et al. (1998), Nollet et al. (1996), Albertsen et al. (United States Patent 6,114,124 issued 2000), Ikawa et al. (1988), McCormick (1999), Buck et al. (1999), and Stratagene (1988).
- 3. The article from the journal Cancer Epidemiology referenced in the declaration as an enclosure was not found in the record and is provided along with the attached PTO-892 form, for entry into the record.

Objections and Rejections that are Withdrawn

Objections and rejections not reiterated herein are hereby withdrawn.
 Applicant's declaration has overcome the rejections under 35 U.S.C. 103.

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Claims Allowed

Claims 1-6, 9, and 11-14 are allowed.

The following is an examiner's statement of reasons for allowance: no prior art was found which teaches or fairly suggests the improved methods and kit for early detection of colon cancer using the panel of primers as claimed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Close

 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Staples/ Primary Examiner, Art Unit 1637 08/11/2010